

SEP 20 2004

**510(k) Summary**  
**IRIDEX Corporation**  
**IRIS Medical® IQ 810**

1/3

K040209

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

John Jossy  
IRIDEX Corporation  
1212 Terra Bella Avenue  
Mountain View, CA 94043  
(650) 962-8848 ext. 3016

Contact Person: (same as above)

Date Prepared: November 3, 2003

**Name of Device and Name/Address of Sponsor**

IRIS Medical® IQ 810 Laser Photocoagulator

IRIDEX Corporation  
1212 Terra Bella Avenue  
Mountain View, CA 94043

**Classification Name**

Laser Instrument, Surgical, Powered  
CFR Section: 886.4390  
Product Code: HQF

**Predicate Devices**

The IQ 810 laser system is substantially equivalent to other currently legally marketed ophthalmology laser devices including IRIDEX Corporation's IRIS Medical OcuLight SLx Laser Photocoagulator (K020374).

**Device Description**

The IQ 810 is a semiconductor diode laser system that delivers infrared 810 nm laser light intended to be used for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and iridotomy. Visible red (630-650 nm) semiconductor diode laser is used for aiming.

## Intended Use

The IQ 810 is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, and other laser diode treatments. The following are examples of applications for the IQ 810 laser systems.

Condition	Treatment
Diabetic Retinopathy <ul style="list-style-type: none"> <li>• Nonproliferative Retinopathy</li> <li>• Macular Edema</li> <li>• Proliferative Retinopathy</li> </ul>	Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments
Glaucoma <ul style="list-style-type: none"> <li>• Primary Open Angle</li> <li>• Closed Angle</li> <li>• Refractory Glaucoma (recalcitrant/uncontrolled)</li> </ul>	Laser Trabeculoplasty; Iridotomy; Transscleral Cyclophotocoagulation (TSCPC)
Retinal Tears, Detachments, and Holes	Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments
Lattice Degeneration	PRP; Focal and Grid Laser Treatments
Age-related Macular Degeneration (AMD) with Choroidal Neovascularization (CNV)	Focal and Grid Laser Treatments
Intra-Ocular Tumors <ul style="list-style-type: none"> <li>• Choroidal Hemangioma</li> <li>• Choroidal Melanoma</li> <li>• Retinoblastoma</li> </ul>	Focal and Grid Laser Treatments
Retinopathy of Prematurity	PRP; TSRPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	PRP; Focal and Grid Laser Treatments

## Technological Characteristics and Substantial Equivalence

The IQ 810 has substantial hardware and software differences from currently marketed laser systems. However, a detailed comparison of the key characteristics between the SLx and the IQ 810 shows that the technology of the IQ 810 does not differ significantly from the predicate device (see Section VII-A-11 of 510k Notification).

The OcuLight SLx Laser System is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and iridotomy.

The OcuLight SLx Laser System delivers similar power, has similar indications, and uses similar delivery devices to that of the IQ 810.

**Non-Clinical performance Data**

None

**Clinical performance Data**

None

**Conclusion**

The IQ 810 is substantially equivalent to predicate devices currently legally marketed for the indication of retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and iridotomy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 20 2004

Mr. John Jossy  
Director, Regulatory Affairs  
and Quality Assurance  
Iridex Corporation  
1212 Terra Bella Avenue  
Mountain View, California 94043-1824

Re: K040209  
Trade/Device Name: IRIS Medical® IQ 810 Diode Laser  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: HQF, GEX  
Dated: August 23, 2004  
Received: August 25, 2004

Dear Mr. Jossy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

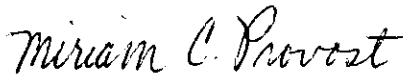
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. John Jossy

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**510(k) Number (if known): ~~Pending~~ K 040209Device Name: IRIS Medical® IQ 810 Laser Photocoagulator**Indications For Use:**

The IRIDEX IQ 810 is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, and other laser diode treatments. The following are examples of applications for the IQ 810.

<b>Condition</b>	<b>Treatment</b>
Diabetic Retinopathy <ul style="list-style-type: none"><li>• Nonproliferative Retinopathy</li><li>• Macular Edema</li><li>• Proliferative Retinopathy</li></ul>	Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments
Glaucoma <ul style="list-style-type: none"><li>• Primary Open Angle</li><li>• Closed Angle</li><li>• Refractory Glaucoma (recalcitrant/uncontrolled)</li></ul>	Laser Trabeculoplasty; Iridotomy, Transscleral Cyclophotocoagulation (TSCPC)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K040209

Prescription Use \_\_\_\_\_

OR  
(Per 21 CFR 801.109)

Over-The-Counter Use \_\_\_\_\_

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K040209Device Name: : IRIS Medical® IQ 810 Laser Photocoagulator

## Indications For Use:

Condition	Treatment
Retinal Tears, Detachments, and Holes	Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments
Lattice Degeneration	PRP; Focal and Grid Laser Treatments
Age-related Macular Degeneration (AMD) with Choroidal Neovascularization (CNV)	Focal and Grid Laser Treatments
Intra-Ocular Tumors <ul style="list-style-type: none"> <li>• Choroidal Hemangioma</li> <li>• Choroidal Melanoma</li> <li>• Retinoblastoma</li> </ul>	Focal and Grid Laser Treatments
Retinopathy of Prematurity	PRP; TSRPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	PRP; Focal and Grid Laser Treatments

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
**(Division Sign-Off)**
**Division of General, Restorative,  
and Neurological Devices**

Prescription Use X **510(k) Number** OR K040209 Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)